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1

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/657,126	09/09/2003	Jean-Francois Bouquet	P06155US02/BAS	9209
<div>7590 06/01/2007 Judy Jarecki-Black, Ph.D., J.D. Merial LTD. 3239 Satellite Blvd. Duluth, GA 30096</div>			<div>EXAMINER ZEMAN, ROBERT A</div>	
			<div>ART UNIT 1645</div>	<div>PAPER NUMBER</div>
			<div>MAIL DATE 06/01/2007</div>	<div>DELIVERY MODE PAPER</div>

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

Application No.

10/657,126

Applicant(s)

BOUQUET ET AL.

Examiner

Robert A. Zeman

Art Unit

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 08 March 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-33 is/are pending in the application.
- 4a) Of the above claim(s) 1-10, 14 and 20-33 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 11-13 and 15-19 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

The amendment and response filed on 3-8-2007 are acknowledged. Claim 1 has been amended. Claims 1-33 are pending. Claims 1-10, 14 and 20-33 are withdrawn from consideration. Claims 11-13 and 15-19 are currently under examination.

#### ***Terminal Disclaimer***

The terminal disclaimer filed on 3-8-2007 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of U.S. Patent 6,255,108 has been reviewed and is accepted. The terminal disclaimer has been recorded.

#### ***Election/Restrictions***

Applicant's continued traversal of the restriction requirement is noted. However, Applicant's traversals were addressed and the restriction requirement was made final in the previous Office action and will not be revisited. Applicant is reminded that they are free to petition the director if they so choose.

Applicant's request for rejoinder of the method claims upon the allowance of elected product claims is also noted.

#### ***Claim Objections Maintained***

The objection to claims 11-12 and 15-17 are objected to as they are drawn in part to non-elected inventions is maintained for reasons of record. Applicant's arguments that said claims are proper since the restriction requirement was improper has been fully considered and deemed

Art Unit: 1645

non-persuasive. As the restriction requirement is deemed proper for the reasons set forth in the previous Office action, the instant claims are drawn, in part, to nonelected inventions.

***Claim Rejections Withdrawn***

The rejection of claims 11-13 and 15-19 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-5 of U.S. Patent No. 6,255,108 is withdrawn in light of the Terminal Disclaimer filed on 3-13-2007.

***Claim Rejections Maintained***

The provisional rejection of claims 12 and 14 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 11, 15-17 and 19 of copending Application No. 11/031,417 is maintained for reasons of record. Applicants have declined to act on this rejection until it is determined whether the claims in the copending application are allowable.

As outlined previously, although the conflicting claims are not identical, they are not patentably distinct from each other because both claim sets are drawn to an avian cell line which are immortalized, but untransformed, comprising in their genome the SV40 T+t gene. Said cell lines can be obtained from avian tissue.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Art Unit: 1645

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The rejection of claims 11-13 and 15-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Evan (WO 93/20200 – IDS filed on 12-18-03) and Givol et al. (Cell Growth & Differentiation, 1994, Vol. 5, pages 419-429) is maintained for reasons of record.

The instant claims are drawn to avian cells (cell line) that are immortalized, but untransformed, comprising an anti-apoptotic bcl-2 gene and optionally the SV40 T+t gene (under the control of the MTI promoter). Said cell lines can be obtained from avian tissues generally, or fibroblasts or epithelial cells specifically.

Art Unit: 1645

**Applicant argues:**

1. Evan does not teach or suggest cells that are untransformed and immortalized.
2. Evan mentions using cells from tumors and presents the hybridoma as its exemplary cell. This teaches away from the instant invention.
3. Evan does not mention or suggest the use of avian cells.
4. Givol relates to chicken embryo cells that are not immortalized.
5. There is no motivation to combine the teachings of the cited references.
6. There would not be a reasonable expectation of successfully arriving at the instant invention using the teachings of Evan and Givol.
7. The state of the art at the time of the invention does not provide any evidence that avian cells could be immortalized using viral oncogenes.

Applicant's arguments have been fully considered and deemed non-persuasive.

With regard to Point 1, it is the combination of the disclosures of Evan and Givol et al. that teaches avian cells that are immortalized but not transformed. Moreover, with regard to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

With regard to Point 2, Applicant is correct that cell lines derived from tumors would necessarily be transformed. However, Evan discloses (and exemplifies) the use of many non-

Art Unit: 1645

tumor derived cell types For example, Evans discloses the establishment of cell lines derived from normal tissues, embryonic tissues, lymphoid cells and haematopoietic cells (see Example 6).

With regard to Point 3, Evan discloses that all cells from multicellular organisms that are cultured can be used in their methods. This encompasses avian fibroblasts.

With regard to Point 4, Evans discloses the desirability of immortalizing cells. Givol discloses the efficacy of using chicken embryo fibroblasts to express bcl-2.

In response to applicant's argument that there is no suggestion to combine the references (Point 5), the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, one would have combined the disclosures of the cited references in order to take advantage of the advantages of immortalized cells lines.

With regard to Points 6 and 7, given that Givol et al. disclose that chicken embryo fibroblasts can be modified to effectively produce bcl-2 by the same means as disclosed by Evans and given that Evans discloses that "all cells from multicellular organisms that are cultured" can be used in their methods and that said cells should be immortalized, the skilled artisan would have had a reasonable expectation of success.

As outlined previously, Evan discloses cells and cell lines comprising a bcl-2 gene wherein said gene is inserted into a vector (see page 19, line 30 to page 20, line 2 and page 20,

Art Unit: 1645

lines 28-29). Evan further discloses that said gene can be episomal or integrated (see page 20, lines 25-26) and that said vector can be used with host cells from any multicellular organism (see page 20, line 18 and page 24, line 30 to page 25, line 1)) and that said host cells should be immortalized (see page 24, lines 25-27).

Evan differs from the instant invention in that he doesn't explicitly disclose the host cells as being obtained from avian tissues generally, or fibroblasts or epithelial cells specifically or that said cells contain the SV40 T+t gene under the control of the MTI promoter (as required by claims 15 and 16).

Givol et al. disclose chicken embryo fibroblasts containing a retroviral vector encoding bcl-2 (see abstract).

Consequently, it would have been obvious for one of ordinary skill in the art at the time the invention was made to utilize chicken embryo fibroblasts as the host cells for the vector disclosed by Evan as their use constitutes an obvious variant of the disclosed invention.

One would have had a reasonable expectation of success as Evan discloses any cell from a multicellular organism can be used in his system and Givol et al. have demonstrated that chicken embryo fibroblasts can be used to express a vector based bcl-2 gene.

With regard to claims 15 and 16, the SV40 T+t gene is commonly used in the art to immortalize cells. Moreover, the MTI promoter is a commonly used promoter. Consequently, their use would have been obvious to the skilled artisan when they immortalized the host cells as disclosed by Evan.



Art Unit: 1645

***Conclusion***

No claim is allowed.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert A. Zeman whose telephone number is (571) 272-0866. The examiner can normally be reached on Monday- Thursday, 7am -5:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on (571) 272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1645

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>.

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ROBERT A. ZEMAN  
PRIMARY EXAMINER

May 28, 2007